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BY HAND DELIVERY

Dockets Management Branch
Food and Drug Administration
Department of Health and Human Services
Room 1061
5630 Fishers Lane
Rockville, MD 20857

Docket No. 98N-0337
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

CITIZEN PETITION OR, IN THE ALTERNATIVE, APPLICATION FOR EXEMPTION

To Whom It May Concern:

On behalf of GlaxoSmithKline (GSK), the undersigned hereby: (1) submit this petition under Sections 502 and 701 of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 201.66(e) to request the Commissioner to amend the final rule providing a partial stay of the compliance dates for "convenience-size" over-the-counter (OTC) drug products (Docket No. 98N-0337, 96N-0420, 95N-0259, and 90P-0201); or, in the alternative, (2) request an exemption from certain OTC drug product labeling requirements contained in 21 C.F.R. § 201.66 ("drug facts rule") for the six dose package of BC® analgesic powder (Docket No. 98N-0337).

98N-0337

APP 43

I. CITIZEN PETITION REQUESTING AMENDMENT TO THE FINAL RULE PROVIDING PARTIAL DELAY IN DRUG FACTS COMPLIANCE DATES

On April 5, 2002, the Food and Drug Administration (FDA) provided a partial delay of the drug facts rule compliance dates for "convenience-size" OTC drug products. 67 Fed.Reg. 16304 (April 5, 2002) ("partial delay final rule"). In that rule, "convenience-size" was defined to comprise drug products that (1) contain no more than two doses of an OTC drug; and (2) because of their limited available labeling space, would require more than 60 percent of the total surface area available to bear required labeling. FDA has indicated that the partial delay will remain in effect until a final rule issues with respect to the labeling of "convenience-size" drug products or until the agency issues further notice. The undersigned hereby requests the Commissioner to: (a) revise the definition of "convenience-size" package and (b) add limited grandfather protection.

A. Revise Definition of "Convenience-Size" Package

The undersigned submit that the definition of "convenience-size" promulgated by FDA in the partial delay final rule is unreasonably narrow and does not include all of the products that should be encompassed within this category. Indeed, the limitation of "convenience-size" to no more than two doses appears to be an arbitrary delineation with no legal or public health justification. The concept of "convenience-size" would seem to refer solely to the size of the package, not the quantity of the contents of the package. Thus, the undersigned submit that the concept of "convenience-size" package, and the concomitant delay, should be extended to products that: (a) consumers purchase for the convenient size; (b) because of their limited available labeling space, would require more than 60 percent of the total surface area available to bear required labeling; and (c) contain not more than eight dosage units.

B. Add Limited Grandfather Protection

The undersigned also submit that the partial stay should be extended to take into account the historical marketing and use of a product and, in particular, the product's distinctive trade dress. Companies invest substantial resources, often over long periods of time, in developing, establishing and maintaining trademarks and trade dress for their products. For instance, the current BC® trade dress has been used continuously for over 25 years and the current package size for the 6 dose package of BC® powder has been used continuously for 70 to 80 years. The brand name, logos, symbols, patterns of colors, and

package size and configuration encompassed by BC®'s trademark and trade dress represent the commercial public identity of BC® powders. GSK has cognizable, protectable property interests in the BC® products' trade dress and companies such as GSK should not be expected to alter the size, shape or layout of the package in a manner that would deprive the company of this valuable property interest.

Accordingly, products that have been on the market for decades that have developed a distinctive trade dress based on the size, shape, and appearance of their small package should also be subject to the partial delay and the special drug facts labeling requirements to be established in a future rule promulgated by the agency. These "grandfathered" products would be limited to those that: (a) were on the market at the time of the initiation of the OTC drug review on May 11, 1972; (b) have a small package size, as defined by FDA (i.e., more than 60 percent of the total surface area available to bear label information would be needed to present the FDA required information); and (c) have developed a distinctive trade dress, as defined by relevant intellectual property law, based on the size, shape and/or design of the package.

C. Summary

The undersigned submit that the partial delay final rule should therefore be amended to: (1) revise the definition of "convenience-size" to include products that: (a) consumers purchase for the convenient size; (b) because of their limited available labeling space, would require more than 60 percent of the total surface area available to bear required labeling; and (c) contain not more than eight dosage units; and (2) include a category of "grandfathered" products that: (a) were on the market at the time of the initiation of the OTC drug review on May 11, 1972; (b) have a small package size, as defined by FDA (i.e., more than 60 percent of the total surface area available to bear label information would be needed to present the FDA required information); and (c) have developed a distinctive trade dress, as defined by relevant intellectual property law, based on the size, shape and/or design of the package.

D. Environmental Impact

According to 21 C.F.R. §25.25(a)(8), this petition qualifies for a categorical exclusion from the requirement for submission of an environmental assessment.

E. Economic Impact

According to 21 C.F.R. § 10.30(b), information on economic impact is to be submitted only when requested by the Commissioner following review of the petition.

F. Certification

The undersigned certify that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data known to the petitioner which are unfavorable to the petition.

II. APPLICATION FOR EXEMPTION TO DRUG FACTS LABELING REQUIREMENTS FOR SIX DOSE PACKAGE OF BC® POWDER

In the alternative, GSK requests an exemption from certain of the OTC labeling requirements in the drug facts rule for the six dose package of BC® analgesic powder.

On January 28, 2000, Block Drug Company, Inc. (Block)[1] submitted an Application for Exemption from certain OTC drug product labeling requirements contained in the drug facts rule for the two dose package of BC® analgesic powder. Block amended this application on August 22, 2000 and December 22, 2000. Because the six dose package of BC® analgesic powder is exactly the same size and shape as the two dose package (see Attachment 1 hereto), the issues presented by the six dose package are identical to those set forth in Block's previous submissions. In this submission, GSK specifically requests an exemption from the format requirements of the drug facts rule as set forth in Option 2 of Block's December 22, 2000 submission. See Appendix 10 to Attachment 2 hereto.

As explained above and in Block's previous submissions, GSK has a protectable property interest in the distinctive trade dress of the six dose package of BC® analgesic powder. Therefore, GSK cannot be expected to alter the size, shape, or overall appearance in any significant manner. Option 2 of Block's December 22, 2000 submission is a legally permissible and reasonable alternative for complying with the OTC labeling format and content requirements.

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[1] BC® analgesic powders are now marketed by GlaxoSmithKline, following the purchase of Block.

Under Option 2, GSK will add a flap or fifth panel that would fold out to display the information that cannot fit on the back of the current package. Because the entire package is shrink-wrapped to make the product tamper-evident, as well as to improve the stability of the product, the information on the inside of the flap or folded fifth panel would not be visible until the shrink-wrap is removed and the flap or panel is unfolded. However, this information would still be available to the consumer at the point of purchase because GSK will provide all of the information required in the standard format required by the drug facts rule on the tray that will be placed on the store shelves to display the product.

Under Option 2 as set forth in Block's December 22, 2000 submission, the BC® outer label will bear all of the information required under the Federal Food, Drug, and Cosmetic Act (Act) to appear on the product's "label," and the fifth panel and the product tray, as the product's "labeling," will bear the remainder of the required information.[2] The only specific information statutorily required to appear on an OTC drug product's label is the name and place of business of the manufacturer, packer, or distributor, the net quantity of contents, the established name of the drug, the active ingredients, and the inactive ingredients. 21 U.S.C. §§ 352(b)(1), (b)(2), (e)(1)(A). All of this information will appear on the BC® outer label and would be visible at point of purchase as set forth in Option 2, together with the lot number and expiration date required by FDA's Good Manufacturing Practice (GMP) regulations.[3]

Whatever authority FDA may or may not have to require a company to provide consumers with the Drug Facts, the agency cannot require that information to appear on a product's label, as opposed to in its labeling, except for the information that is statutorily required to appear on the label. See, e.g., Association of American Physicians and Surgeons, Inc. v. FDA, 2002 WL 31323411, No. CIV.A.00-02898 (HHK) (D.D.C. October 17, 2002) (FDA's authority is limited to that provided by Congress in the Act) (citing ACLU v. FCC, 823 F.2d 1554 (D.C.Cir. 1987)). The other required information,

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[2] The Act defines the "label" as a "display of written, printed or graphic matter upon the immediate container of any article." 21 U.S.C. § 321(k). "Labeling" is defined as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 U.S.C. § 321(m).

[3] As part of its request for exemption, GSK requests that it be permitted to change the order of the information presented in the Drug Facts box so that the inactive ingredients will appear on the label immediately following the active ingredients. In addition, GSK is willing to place the salicylates warning statement on the outer label of the product, regardless of whether this is required under the Act. Accordingly, GSK requests that it be permitted to change the order of the information presented in the Drug Facts box so that this warning appears directly after the Reye's syndrome warning.

such as adequate directions for use and certain warning statements, may be contained either on the label or otherwise in the product's labeling. 21 U.S.C. § 352(f). Thus, a drug would not be misbranded under Section 502 of the Act if this information appears in the product's labeling that accompanies the product. This would be the case under Option 2.

Option 2 achieves all of FDA's objectives: (1) it provides the consumer with all of the relevant information at the point of purchase so that the consumer can make an informed purchasing decision; (2) it ensures that the consumer has the relevant information at the time of use of the product so that the product will be used safely and effectively; and (3) it protects GSK's valuable property interest in the distinctive trade dress of the six dose package of BC® analgesic powder. GSK's proposed use of both the fifth flap and the product tray would enable the consumer to have the information relevant to purchase and use of the product at both the time of purchase and the time of use.[4]

III. CONCLUSION

The BC® trade dress, including the size, shape and layout of the six dose package, has been developed and maintained over many years and has substantial commercial value to GSK. It would be a violation of the Fifth Amendment to the United States Constitution to require GSK to substantially alter this trade dress, particularly where the legal requirements pertaining to OTC drug product labels and labeling would be met by alternative methods.

Accordingly, on behalf of GSK, the undersigned hereby request an amendment to the partial delay final rule to: (1) revise the definition of "convenience-size" to include products that: (a) consumers purchase for the convenient size; (b) because of their limited available labeling space, would require more than 60 percent of the total surface area available to bear required labeling; and (c) contain not more than eight dosage units; and (2) include a category of "grandfathered" products that: (a) were on the market at the time of the initiation of the OTC drug review on May 11, 1972; (b) have a small package size, as defined by FDA (i.e., more than 60 percent of the total surface area available to bear label information would be needed to present the FDA required information); and (c) have developed a distinctive trade dress, as defined by relevant intellectual property law, based on the size, shape and/or design of the package. In the alternative, the

[4] To further these objectives, GSK is willing to include a statement on the product tray that the consumer should be sure to read all of the warnings and directions for use on the inside of the fifth flap prior to use of the product. In addition, GSK is willing to instruct retailers to retain the product tray to display the product as long as the product is being sold by the retailer.

undersigned request an exemption from certain OTC drug product labeling requirements in order to implement Option 2 (as set forth in Block's December 22, 2000 submission to the docket) for the six dose package of BC® analgesic powder.

Please do not hesitate to contact us if you would like to discuss our requests or if you have any questions.

Sincerely,

Thomas O. Henteleff
Stacy L. Ehrlich

TOH:SLE/s